

REMARKS

Applicant respectfully requests reconsideration. Claims 140-159 were previously pending in this application. Claims 140, 143, 144, 147, 150, 151, 154, 157 and 158 have been amended. Support for the claim amendments can be found throughout the instant specification (e.g., on page 31) and in the claims as originally filed. As a result, claims 140-159 are pending for examination with claims 140, 147 and 154 being independent claims and claims 142, 149 and 156 being withdrawn from consideration.

As indicated in the previous amendment, claims 1, 28 and 55 were rewritten as new claims 140, 147 and 154 with the addition of claim limitations of canceled claims.

No new matter has been added.

Rejections under 35 U.S.C. §112

Claims 140, 141, 143-148, 150-155 and 157-159 are rejected under 35 U.S.C. §112 for an alleged failure to comply with the written description requirement. The Examiner has argued that the specification does not provide a reasonably representative disclosure of useful lysine derivatives and glutamine derivatives. The Examiner further alleges that it is unclear if the linking molecule requires the lysine or glutamine in specific locations or how far derived the linking molecule may be and still be a substrate of transglutaminase.

Without conceding the correctness of this rejection, Applicant has amended the claims to remove the recitation of derivatives of lysine and derivatives of glutamine. In addition, Applicant notes that the claims define the linking molecule that is a substrate of transglutaminase as comprising at least two contiguous aliphatic amines or two contiguous carboxamides, wherein the aliphatic amines are lysines and the carboxamides are glutamines. Thus, the linking molecules that are a substrate of transglutaminase are defined by structural features common to the members of the genus such that one of ordinary skill in the art would be able to “visualize or recognize” the members of the genus. The written description requirement is, therefore, satisfied. Amgen, Inc. v. Hoechst Marion Roussel, Inc et al., 314 F.3d 1313 (Fed. Cir. 2003).

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §102

Claims 147, 148, 150 and 151 are rejected under 35 U.S.C. §102 as allegedly being anticipated by Asayama (Bioconjugate Chem., 9:476-81, 1998).

Without conceding the correctness of this rejection, Applicant has amended claim 147 so that the amount of the conjugate of hyaluronic acid and linking molecule in the pharmaceutical composition must be effective to treat dry eye or dry mouth. This feature, which is not disclosed in Asayama, is now clearly recited as a limitation in the rejected claims. Accordingly, the cited reference does not teach all of the features of the composition of the claims and, therefore, does not anticipate the rejected claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 147, 148, 150-155, 157 and 158 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Green (U.S. Patent No. 6,267,957).

Without conceding the correctness of this rejection, Applicant has amended claim 147 to recite that the composition comprises a solution comprising the conjugate of hyaluronic acid and linking molecule and that such conjugate is in an amount effective to treat dry eye or dry mouth. The Examiner has not demonstrated, from the teachings of Green, that one of ordinary skill in the art would have any reason to produce a composition of a conjugate of hyaluronic acid and linking molecule as recited in the rejected claims 1) that is in a solution (as required in independent claim 147), 2) that is in an eye dropper bottle (as required in independent claim 154) or 3) that comprises the conjugate in an amount effective to treat dry eye or dry mouth (as required in independent claim 147).

The hyaluronic acid of Green is provided as an example of a tissue sealant. The Examiner has not demonstrated that there would be any reason for one of ordinary skill in the art to take a conjugate of this tissue sealant and prepare a composition of the rejected claims. The Examiner has argued that Green teaches that its conjugate may be in the form of an eye dropping solution, ophthalmic ointment or contact lens solution and, thus, it is clear that the composition can be used for the eye and in the form of an eye dropper. However, no recitation of an eye dropping solution,

ophthalmic ointment or contact lens solution can be found in Green as the Examiner has argued. In addition, no reason to attach the tissue sealant conjugate of Green to the eye is provided. A general recitation of the surfaces to which agents may be attached, such as the eye, is not a teaching that would lead one of ordinary skill in the art to attach each and every agent of the numerous agents listed in Green to any and all of the recited surfaces. When prior art discloses a vast number of possibilities there must be something in the prior art to “narrow the possibilities” to the particular possibility that is to form the basis of an obviousness rejection. Takeda Chemical Industries, LTD. v. Alphapharm PTY., LTD., 492 F.3d 1350 (Fed. Cir. 2007). Certainly, there are no teachings in the cited reference, or otherwise offered by the Examiner, that indicate that the conjugates of the tissue sealants would be useful or even appropriate for application to the eye. Thus, there would be no reason for one of ordinary skill in the art to modify the teachings of Green to obtain the compositions of the claims as the Examiner has suggested.

The Examiner has also argued that it does not appear that the claims recite the limitation that the conjugate formulation is in the form of a solution. Applicant has amended claim 147 to recite that the composition comprises a solution comprising the conjugate, and as argued above Green does not teach the composition may be in the form of an eye dropper or contact lens solution.

The Examiner further noted that treating dry eye is not recited in the claims, and even if it were, the recitation would be viewed as an intended use. Claim 147 has been amended to recite that the amount of the conjugate is effective to treat dry eye or dry mouth. Such an amount is a limiting feature of the composition of claim 147, and there is no demonstration that such amount is taught or suggested by the teachings of Green.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 140, 141, 143-148, 150-155 and 157-159 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Green (U.S. Patent No. 6,267,957) in view of Cantoro (U.S. Patent No. 5,770,628).

As argued above, the teachings of Green fail to teach or suggest the compositions of the claims. In addition, the teachings of Cantoro fail to remedy the deficiencies of Green. The Examiner has suggested that it would have been obvious to adjust the amount of free hyaluronic

acid in order to obtain a solution having a desired viscosity, given that Cantoro teaches hyaluronic acid acts as a thickener. However, no link between the tissue sealants of Green and ophthalmic uses is provided. In addition, the Examiner has not demonstrated that there would be any reason for one of ordinary skill in the art to use the free hyaluronic acid as suggested in Cantoro in order to adjust the viscosity of a tissue sealant conjugate composition. Accordingly, there is no reason for one of ordinary skill in the art to combine the teachings of the cited references to obtain the compositions of the claims.

Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. H0535.70016US00 from which the undersigned is authorized to draw.

Dated: December 10, 2010

Respectfully submitted,

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